CENTER FOR HEALTHCARE INNOVATION AND PATIENT OUTCOMES RESEARCH

Samford University
McWhorter School of Pharmacy

NEW DRUG FAX SHEET

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This issue of *New Drug FAX Sheet* briefly reviews topics that include new drug approvals, new drug formulations, and new drug indications. If you need further information, please contact the Center for Healthcare Innovation and Patient Outcomes Research (CHIPOR) at chipor@samford.edu.

NEW DRUG APPROVALS

Dupilumab (Dupixent, Regeneron Pharmaceuticals)
Pharmacology: Interleukin-4-receptor alpha antagonist.
Indication: Treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other therapies.
Adverse Drug Reactions: Injection site reactions, conjunctivitis, blepharitis, oral herpes, keratitis, eye pruritus, other herpes simplex virus infection, and dry eye.
Dose: 300 mg / 2 mL solution.
Formulation: Injection.
Warnings/Contraindications: Hypersensitivity, conjunctivitis and keratitis; comorbid asthma.
Notes: Avoid use of live vaccines with concomitant dupilumab administration. Interactions with CYP450 substrates may occur, especially those medications with a narrow therapeutic index. Monitor for increased/decreased drug effects or changes in drug concentration. Consider dosage modification, if necessary.

Ocrelizumab (Ocrevus, Genetech Pharmaceuticals)
Pharmacology: CD20-directed cytolytic antibody.
Indication: Treatment of patients with relapsing or primary progressive forms of multiple sclerosis (MS).
Adverse Drug Reactions: Relapsing MS (RMS) - upper respiratory tract infections and infusion reactions. Primary progressive MS (PPMS) - upper respiratory tract infections, infusion reactions, skin infections, and lower respiratory tract infections.
Dose: 300 mg with increasing doses of 600 mg every 6 months.
Formulation: 300 mg/10 mL injection in a single-dose vial.
Warnings/Contraindications: Infusion reactions, infections, increased malignancies.
Notes: Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation until B-cell repletion.

Avelumab (Bavencio, EMD Serono Inc)
Pharmacology: Programmed death ligand-1 (PD-L1) blocking antibody.
Indication: Treatment of adults and pediatric patients (12 years and older) with metastatic Merkel cell carcinoma.
Adverse Drug Reactions: Fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, rash, decreased appetite, and peripheral edema.
Dose: 10 mg/kg every 2 weeks.
Formulation: 200 mg/10 mL injection.
Warnings/Contraindications: Immune-mediated pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, infusion-related reactions, and embryo-fetal toxicity.
Notes: Premedicate with acetaminophen and an antihistamine for the first 4 infusions and as needed.

Ribociclib (Kisqali, Novartis Pharmaceuticals)
Pharmacology: Kinase inhibitor.
Indication: Treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, in combination with an aromatase inhibitor.
Adverse Drug Reactions: Neutropenia, nausea, fatigue, diarrhea, leukopenia, alopecia, vomiting, constipation, headache, and back pain.

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Ribociclib (Kisqali, Novartis Pharmaceuticals) (continued)
Dose: 200 mg.
Formulation: Tablets.
Warnings/Contraindications: QT interval prolongation, hepatobiliary toxicity, neutropenia, and embryo-fetal toxicity.
Notes: Significant drug-drug interactions with strong CYP3A inhibitors, CYPE3A4 inducers, CYP3A substrates, and drugs known to prolong QT interval.

Safinamide (Xadago, Newron Pharmaceuticals)
Pharmacology: Monoamine oxidase type B MAO-B inhibitor.
Indication: Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.
Adverse Drug Reactions: Dyskinesia, fall, nausea, insomnia.
Dose: 50 mg once daily; can be increased to 100 mg once daily after 2 weeks.
Formulation: 50- and 100-mg tablets.
Warnings/Contraindications: May cause/exacerbate hypertension; may cause serotonin syndrome when used with MAO inhibitors, antidepressants, or opioid drugs; may cause falling asleep; may cause/exacerbate dyskinesia; may cause hallucinations; may cause problems with impulse control/compulsive behaviors; and may cause withdrawal-emergent hyperpyrexia and confusion.
Notes: Drug-drug interactions may occur with concomitant use of selective serotonin reuptake inhibitors; sympathomimetic medications; tyramine; substrates of breast cancer resistance protein (BCRP).

Naldemedine (Symproic, Shionogi Pharmaceuticals)
Pharmacology: Opioid antagonist.
Indication: Treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain.
Adverse Drug Reactions: Abdominal pain, diarrhea, and nausea.
Dose: 0.2 mg daily with or without food.
Formulation: 0.2-mg tablet.
Warnings/Contraindications: Gastrointestinal perforation and opioid withdrawal.
Notes: Concomitant use should be avoided with strong CYP3A inducers and opioid antagonists. Other drug-drug interactions include moderate and strong CYP3A4 inhibitors, and P-gp inhibitors.

Niraparib (Zejula, Tesaro Pharmaceuticals)
Pharmacology: Poly (ADP-ribose) polymerase (PARP) inhibitor.
Indication: Maintenance treatment of adult patients with recurrent epithelia ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
Adverse Drug Reactions: Thrombocytopenia, anemia, neutropenia, leukopenia, palpitations, nausea, constipation, etc.
Dose: 300 mg taken once daily with or without food.
Formulation: 100-mg capsules.
Warnings/Contraindications: Myelodysplastic syndrome/acute myeloid leukemia, bone marrow suppression, cardiovascular effects; and embryo-fetal toxicity.
Notes: Treatment should be continued until disease progression or unacceptable adverse reaction. For adverse reactions, consider interruption of treatment, dose reduction, or dose discontinuation.

NEW DRUG FORMULATIONS

Ephedrine Sulfate (Ephedrine Sulfate, Akorn Inc)
Pharmacology: Alpha-and beta-adrenergic agonist and a norepinephrine-releasing agent.
Indication: Treatment of clinically important hypotension upon the receipt of anesthesia.
Dosage form: 50 mg/mL injection.
Dose: 5-10 mg bolus intravenous injection; do not exceed 50 mg.

Desmopressin Acetate (Noctiva, Serenity Pharms LLC)
Pharmacology: Vasopressin analog.
Indication: Treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.
Dosage form: Preservative-free nasal spray.
Dose: 0.83 mcg night and 1.66 mcg after at least 7 days.

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Sodium Nitroprusside (Nipride RTU, Exela Pharma Science)
Pharmacology: Direct acting vasodilator.
Indication: Immediate reduction of blood pressure; producing controlled hypotension to reduce bleeding during surgery; and treatment of acute heart failure.
Dosage form: Injection 50 mg in 100 mL of 0.9% sodium chloride in 100 mL single-use vials.
Dose: Initiate sodium nitroprusside at a rate of 0.3 mcg/kg/min and titrate to the desired effect.

Voriconazole (Voriconazole, Xellia Pharms APS)
Pharmacology: Azole antifungal.
Indication: Invasive aspergillosis; candidemia and disseminated candidiasis in skin, abdomen, kidney, bladder wall and wounds; serious infection caused by *Scedosporium apiospermum* and *Fusarium* species.
Dosage form: Lyophilized powder containing 200 mg voriconazole.
Dose: Varies depending on indication. The typical dose is 6 mg/kg every 12 hours for the first 24 hours and then 4 mg/kg every 12 hours.

Lamivudine and Zidovudine (Lamivudine; Zidovudine, Pharmacare LTD)
Pharmacology: Combination of two nucleoside analogue reverse transcriptase inhibitors.
Indication: Treatment of HIV-1 infection in combination with other antiretroviral agents.
Dosage form: Tablets containing lamivudine 150 mg and zidovudine 300 mg.
Dose: Adults and adolescents weighing over or equal to 30 kg, administer 1 tablet orally twice daily.

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